REMARKS/ARGUMENTS

Claims 1, 22, 23 and 33- 37 are amended to recite alternative versions of the names of the components of the invention that are well established in the art. In accordance with MPEP 2173.01, these amendments are not made for reasons of patentability because a fundamental principle contained in 35 U.S.C. 112, second paragraph, is that applicants are their own lexicographers.

A supplemental Information Disclosure Statement and a fee are submitted herewith.

With respect to the claim rejections under 35 U.S.C. 112, first paragraph, applicant has enclosed with this amendment as Exhibit A a declaration by the applicant that the specific strain designated as *Bacillus amyloliquefaciens* TJ1000 or 1BE has been deposited under the Budapest Treaty with the ATCC and all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. Applicant notes that a declaration to this effect is already made at page 26, lines 7-19, of the specification.

With respect to the claim rejections under 35 U.S.C. 112, second paragraph, applicant points out that the designation "*Bacillus amyloliquefaciens* TJ1000 or 1BE (ATCC BAA-390)" contains both the laboratory/strain designation for the microorganism recited in the claims and the ATCC accession number for that microorganism. The specification at page 26, lines 7-19,

makes it clear that the designated microorganism is a single strain that was referred to using a different designation in the applicant's provisional application. Because the designation "*Bacillus amyloliquefaciens* TJ1000 or 1BE (ATCC BAA-390)" is the designation used by the ATCC, it has a defined meaning in the art.

With respect to the claim rejections under 35 U.S.C. 103, the applicant notes that the claimed invention is not obvious in view of Shanmuganathan (5,525,132), Ocamb et al. (6,133,196) and Neyra et al. (5,697,186). In the remainder of this response, the applicant shows the following:

(1) that the cited patents do not "teach or suggest all the claim limitations" as required by MPEP 2143.03;

(2) that the cited references and other references teach away from the invention;

(3) that the invention produces unexpected results;

(4) that the claimed invention solves long-felt but unsolved needs and overcomes the failure of others; and

(4) that the invention is commercially successful.

The cited references do not "all teach combining diverse microorganisms together to make biocontrol compositions for application to plants (or parts thereof)." Neither does applicant claim such subject matter.

Specifically, Shanmuganathan (5,525,132) teaches "compositions for the treatment/prevention of microbial diseases of fruit comprising as effective amount of at least one yeast strain . . ." (Abstract). In Example 2, strains are tested separately and are not combined. The disclosed strain D9 was effective and *Trichoderma viridie* was not. Neither was *Bacillus subtilis* effective. The reference teaches that "it is very unpredictable whether a particular yeast species would be effective in the treatment/prevention of microbial disease in fruit" (col. 2, lines 26-28).

Similarly, Neyra et al. (5,697,186) teach "flocculated bacterial cells" for use "as high-density crop inoculants" (Abstract). The reference is limited to the flocculation of one or more species of bacteria. Combination of bacteria with another type of microorganism is not taught by the reference. Nor, does it teach the combination of more than one bacterium will produce a greater response, only that the flocculation will allow the application of more than one bacteria for whatever reason.

Ocamb et al. (6,133,196) teach contacting conifer seeds with a culture of certain bacteria, drying the seeds, planting the seeds and then treating the plant growth medium with a certain ectomycorrhizal fungus (Hebeloma spp.). The reference does not teach treating seeds with a composition comprising a fungus and a bacterium.

Neither do the references reviewed in the specification teach the compositions claimed by the applicant. U.S. Patent No. 6,232,270 discloses a *B. amyloliquefaciens* species that is not the strain recited in applicant's claims. Moreover, combination of the different strain with a chemical agent (e.g., a plant growth stunting agent, herbicide , systemic fungicide) is required by

the reference. There is no disclosure of an effect of the strain alone or in applicant's claimed combination. In U.S. Patent No. 6,326,016, the *B. amyloliquefaciens* species and Trichoderma species cited are not the strains recited in applicant's claims. Production of an extract is required and high-temperature autoclaving is required by the reference. There is no disclosure of an effect alone or in applicant's claimed combinations. In the Stratsoy Research Database reference, the *B. amyloliquefaciens* species cited is not the strain recited in applicant's claims. Similary, with respect the fungus, in all reviewed references, none of the fungus species cited are recited in applicant's claims. Given the unpredictable nature of the biocontrol art, none of the references render the claimed compositions obvious

It is also helpful to clarify the relevance of the teachings of the cases cited by the Examiner. The Crocket case teaches "Prior art teaches use of magnesium oxide and calcium carbide individually; assuming that the two together produce an effect somewhat greater than sum of their separate effects, idea of combining them would flow logically from teaching of prior art; therefore, claim to their joint use is not patentable." This rule is not applicable in this situation because (1) the prior art does not teach use of the recited microorganisms individually, and (2) the idea of combining them does not flow logically from the teachings of the prior art.

The Sussman case teaches "Application for patent for alleged invention relating to pretonsorial preparation for application to skin before shaving was properly rejected as not patentable over prior art in view of fact that each of the ingredients in the preparation functioned precisely as was to be expected from teachings of prior art." This rule is not applicable in this situation because no expectation of how each of the microorganisms recited in the applicant's

claims would function separately is disclosed in the prior art.

The applicant has enclosed with this amendment a supplemental Information Disclosure Statement and a fee in order to place in the record other prior art that teaches away from the claimed invention. Preferred embodiments of the claimed invention comprise combining of a *Trichoderma virens* fungi and a *Bacillus subtillus* var. *amyloliquefaciens* bacteria and placing this combination on a seed or in the vicinity of the seed or seedling. The specific isolates/strains involved are: *T. virens* isolate Gl-3 and *B. subtilis* var. *amyloliquifaciens* strain TJ 1000. In a paper entitled Mechanism in the biocontrol of *Rhizoctonia solani* – induced cotton seedling disease by *Gliocladium virens*: antibiosis by C. R. Howell and R. D. Stipanovic, Phytopathology 85 469-472, 1995, the authors discuss the fact that *Gliocladium virens* (*Trichoderma virens* and *Gliocladium virens* are synonymous) produces a substance called "gliotoxin." In this paper, the organism that was used to test for the presence or absence of gliotoxin production was *Bacillus subtilis* because gliotoxin inhibits the growth of *Bacillus subtilis*.

Because the *Trichoderma virens* Gl-3 of the claimed invention is known to produce gliotoxin and it has remained in its wild state in preferred claimed embodiments, it is not only nonobvious that a strain of *Bacillus subtilis* var. *amyloliquifaciens* would produce a synergistic effect, one skilled in the art would understand that this reference teaches away from the claimed combination as an effective means to produce a synergistic effect. Thus, the applicant's invention not only produces surprising results by creating a synergistic effect between the two organisms, the claimed invention also solves several problems that were encountered in the prior art.

The applicant has enclosed with this amendment as Exhibit B a declaration by the applicant that provides evidence of secondary considerations that render the invention nonobvious. One type of evidence provided in the declaration shows that the invention solves long-felt but unsolved needs and overcomes the failure of others. Specifically, the claimed invention does not contain a bacterium that has been implicated in complicating cystic fibrosis and the claimed invention does contain a spore-forming bacterium, allowing seeds coated with the claimed combination to be stored much longer before planting.

Another type of evidence provided in the declaration shows that the invention produces results that would have been unexpected to one of ordinary skill. Specifically, this evidence shows that the claimed combination causes plants that are derived from seeds treated with the claimed combination to take up more manganese from the soil. One having ordinary skill in the art would know that plants having a higher manganese content are protected from fungal diseases. That routineer would not expect, however, that seed treatment with either microorganism component of the combination does not increase manganese intake, but seed treatment with the claimed combination does increase manganese intake.

Other evidence shows that seed treatment with the claimed combination produces more consistent increases in yield. Specifically, the claimed combination produces: (1) consistency compared to either organism alone, in that the disclosed field trial results show the claimed combination to be significantly higher in yield in both individual locations and multiple location than either organism alone; (2) consistency across geography, in that the disclosed field trial

results show the combination to be effective in a number of geographies from North Dakota to Arizona; and (3) consistency of higher yield in a more than one crop, in that the disclosed field data collected on corn, soybeans, sunflowers and wheat show significant increased in yield with the claimed combination.

These lines of evidence disproves the Examiner's assertion that "the results obtained thereby are no more than the additive effect of the ingredients" upon which he based his prima facie determination of obviousness. The affiant is shown to be one of ordinary skill in the art. As stated by the Federal Circuit:

> "One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e. to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basis principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. The principle applies most often to the less predicable fields, such as chemistry, where minor changes in a product or process ~~many~~ yield substantially different results" *In re* Soni, 54 F.3d 746, 34 USPQ 2d 1684, 1687 (Fed. Cir. 1995).

Another line of evidence shows that products that embody the invention have achieved commercial success because of the presence in the products of the claimed combination. Specifically, TJ Technologies, Inc., a business owned by the applicant has received a $397,890 Phase II and a $350,000 Phase IIB Small Business Innovation Research (SBIR) award from the

National Science Foundation for field trials of the claimed combination after a feasibility study performed under a $99,473 Phase I SBIR award proved the feasibility of the concept. All three of these awards were made in a national competition for Federal research and development funding.

The commercial success of the claimed combination is also shown by the success of a test market conducted in November and December of 2003. This test market illustrates the tremendous need and acceptance for the solution this product brings to the agriculture industry. No factor other than the benefits of the claimed invention is responsible for this commercial success, and, thus, a nexus exists between the claimed invention and the commercial success.

New claims 45 and 46 are added to Group I in that they effectively include all the limitations of other claims in Group I. No other combination comprising a fungus and a bacterium are known to function in the ways claimed in claims 45 and 46.

Based on the above showings, the applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required during the entire pendency of this application to Deposit Account No. 500593.

Respectfully submitted,

ROBERT M. HUNTER PLLC

By: Robert M. Hunter

Robert M. Hunter
Reg. No. 42,679
Tel.: (808) 885-4194